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Application Number

09/802,376

Filing Date

March 9, 2001

First Named Inventor

Gary Van NEST, et al.

Group Art Unit

1635

Examiner Name

J. Zara

Attorney Docket No.

377882001700

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25225

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SIGNATURE OF APPLICANT, ATTORNEY OR AGENT

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Karen R. Zachow

Date

February 11, 2003

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PATENT
Docket No. 377882001700

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Rhea Amid
Rhea Amid

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Gary VAN NEST and Stephen TUCK

Serial No.: 09/802,376

Filing Date: March 9, 2001

For: IMMUNOMODULATORY
FORMULATIONS AND METHODS
FOR USE THEREOF

Examiner: J. Zara

Group Art Unit: 1635

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RESPONSE TO RESTRICTION REQUIREMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

This is in response to the Office Action dated January 24, 2003 (Paper No. 12) which sets forth a restriction requirement for pending claims 1-66 in the above-identified application. A response to this action is due February 24, 2003. Accordingly, this response is timely filed.

ELECTION OF INVENTION

In the pending Office Action, the restriction set forth in Paper No. 9, mailed October 3, 2002, is vacated and a new restriction requirement is set forth.

Claims 1-66 are pending in this application. Restriction has been required as between the following allegedly distinct groups of inventions:

Group I (claims 1-11 and 56-66): drawn to compositions comprising an IMP/MC complex; and

Group II (claims 12-55): drawn to methods of immune modulation.

Applicants traverse this restriction requirement on the grounds that the Examiner has not provided adequate support for the division of Groups I and II according to M.P.E.P. §§ 806.03; 806.04.

The separation of the claims of Groups I and II is allegedly supported with the statement that "the different inventions I and II are biologically and functionally different and distinct from each other." Office Action, page 3. Applicants respectfully disagree with this general statement. The product of the Group I claims is an immunomodulatory polynucleotide/microcarrier (IMP/MC) complex comprising a polynucleotide comprising an immunostimulatory sequence linked to a nonbiodegradable microcarrier. The claims of Group II are drawn to a method of modulating an immune response comprising administering an IMP/MC complex. Applicants request that the Examiner support the assertion that the product (Group I) and the method of using the product (Group II) are distinct inventions or withdraw the requirement to separate groups (M.P.E.P. §806.05(h)).

Further, Applicants respectfully traverse the classification differences of Groups I and II. For example, the classification definitions of the Office list compositions in class 435 as involving "immobilized or insolubilized enzyme or a test or culture media." Applicants submit that nothing in the claims leads one to classify the claims of Group I into class 435. Applicants request the Examiner explain the basis for distinguishing the classification of these two groups, when the claimed components are very similar.